

REMARKS

Claims 1-9, 11-28, and 34-43 are currently pending in the application. Claims 1, 16 and 36 have been amended. Consideration of this Amendment After Final is respectfully requested under 37 C.F.R. § 1.116. The Amendment places the claims in allowable form and/or places the claims in better form for consideration on appeal.

Initially in the Office Action, the Examiner noted that in the prior amendment that claim 42 was indicated as amended, but apparently the change was not indicated in claim 42. Applicants would like to draw the Examiner's attention back to the Amendment that was filed on June 18, 2004 and claim 42. The article "a" included a strikethrough (which is a little difficult to see), thereby eliminating the article "a" from the claim. Claim 42 is herein identified in this amendment as "previously presented". The strikethrough was made and therefore it is believed the amendment was made in the June 18, 2004 amendment. Applicants request that the Examiner acknowledge that this amendment was made in the Amendment dated June 18, 2004.

On page 2 of the Office Action, claims 1-9, 11-28, and 34-43 are rejected under 35 U.S.C. § 112, second paragraph for being indefinite.

The Examiner has alleged that the phrase "generally non-reactive" in line 4 of claim 1 and wherever cited in other claims is uncertain as to meaning and scope. More specifically, the

Examiner believes that this phrase is uncertain as to amount of non-reactivity required and reactivity excluded by the term "generally" and that because of this, the term is vague, and its metes and bounds are relative and subjective.

It is believed that the term "generally non-reactive" is certain and complies with the meaning of 35 U.S.C. §112. MPEP § 2173.05(b) states that "the fact that claim language, including terms of degree may not be precise, does not automatically render the claim indefinite under 35 U.S.C. § 112, 2nd paragraph. Although the MPEP does not expressly discuss the use of the word "generally", it does discuss the word "substantially", which is similar to the word "generally" when used as a modifier for a claim element. For example, if the word "substantially" was substituted for the word "generally" in claim 1, the phrase "substantially non-reactive" would mean the same as "generally non-reactive" and is definite. One skilled in the art would understand what "substantially non-reactive" means. Likewise one skilled in the art would know what "generally non-reactive" means. Both phrases limit the reactivity of the functional groups with other bridges, so the bridges can function as bridges.

The Examiner also stated that the claims were further unclear by the phrase "the functional groups" in claim 1 (line 3), and were recited in other claims. The Examiner suggested that claim 1 be amended in line 2 by changing "bridges bonded" to--- bridges having functional groups bonded by the functional groups ---. Independent claim 1 has been so amended along with

the other independent claims, claims 16 and 36.

In view of the above, it is respectfully requested that the rejection under 35 U.S.C. §112, second paragraph be withdrawn.

Rejection Under 35 U.S.C. § 103

On page 3 of the Office Action, claims 1-9, 11-28, and 34-43 are rejected under 35 U.S.C. §103(a) as being unpatentable over Ogle, et al. (U.S. Patent No. 5,958,669) in view of Yang, et al. (U.S. Patent No. 5,935,168). Applicants respectfully traverse the rejections.

The Examiner has alleged that the Ogle et al. '669 patent discloses crosslinking tissue to fix tissue by reacting the tissue with glutaraldehyde. The Examiner then states that Yang et al. discloses crosslinking tissue with glutaraldehyde, and then reacting with a diamine followed by reacting with additional glutaraldehyde. The Examiner suggests that the diamine of Yang et al. will act as a linker while the glutaraldehyde would be the bridge. Additionally, then some of the diamine groups will react with some free aldehyde groups of the glutaraldehyde which will result in the glutaraldehyde being a linker and the diamine being a bridge. Finally, the Examiner states that the aldehyde groups of a glutaraldehyde are generally non-reactive with other aldehyde groups of another glutaraldehyde and that the amine groups of a diamine will not react with amine groups of another diamine. Therefore, a bridge will not react with another bridge.

The Examiner has found applicant's previous argument as unpersuasive asserting that polymerizing of the dialdehyde occurs

only under certain conditions and that those conditions can be controlled such that it occurs to an extent to be generally non-reactive. Furthermore, the Examiner asserts that this self-polymerizing is not due to covalent bonding between functional groups but is due to attractive forces between bonds similar to adsorption. Therefore, functional groups of a glutaraldehyde molecule will not be expected to covalently react with the functional groups of another glutaraldehyde molecule. The Examiner asserts all of this without any citation.

Attached to this response is an article by John A. Kiernan, entitled "Formaldehyde, Formalin, Paraformaldehyde and Glutaraldehyde: What They Are and What They Do", Microscopy Today 00-1 pp. 8-12 (2000). Self-polymerization of glutaraldehyde is discussed along with an illustration of the reaction equation on pages 2 and 3 of Kiernan. The Kiernan article clearly shows covalent bonding occurring between monomers and oligomers of glutaraldehyde. Self-polymerization of glutaraldehyde through the aldehyde groups is necessary in its function as a fixation agent. If self-polymerization did not occur, then glutaraldehyde would not be the fixative that it is widely known for. The resulting polymer has to have strong covalent bonds to have the necessary integrity to act as a fixation agent. Of course, the free aldehydes of the polymerized glutaraldehyde react with the nitrogen of the underlying tissue to fix the tissue to the polymerized glutaraldehyde. The Examiner's statement that glutaraldehyde molecules are not expected to covalently react

with the functional groups of another glutaraldehyde molecule (which is the aldehyde molecule) is not understood. Reaction between aldehyde molecules readily occurs. One problem relating to the use of glutaraldehyde as a fixation agent is that it can self-polymerize too quickly, making the molecular chains too long to act as a suitable fixation agent. The Examiner's statement relating to attractive forces being similar to adsorption is also not understood. The Examiner is requested to provide citations for these mechanisms.

Furthermore, the combination where the Examiner suggests that the diamine would be a linker and the glutaraldehyde would be a bridge would not function since the aldehyde groups of the glutaraldehyde would not only react with diamines but also with any other primary nitrogens in the tissue. Therefore, the glutaraldehyde would not act as a bridge but as a fixation agent by completely covering and encompassing the diamines reacting with both the diamines and nitrogen of the tissue.

With regard to the combination that the Examiner has made alleging the existence of both diamine bridges and glutaraldehyde bridges, these bridges would then react with each other since glutaraldehyde readily reacts with the nitrogen of the diamines.

In view of the above, the rejection that the Examiner has made under 35 U.S.C. §103 (a) cannot be maintained.

Applicants respectfully request withdrawal of the rejection of claims 1-9, 11-28, and 34-43 under 35 U.S.C. § 103(a) as being obvious by Ogle, et al. in view of Yang, et al and allowance of

the claims.

In view of the amendments and reasons provided above, it is believed that all pending claims are in condition for allowance. Applicants respectfully request favorable reconsideration and early allowance of all pending claims.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicants' attorney of record, Hallie A. Finucane at (612) 330-0587.

A petition for a one-month extension of time is hereby requested. A check in the amount of \$120.00 is enclosed herewith for the extension fee.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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